UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

VALUE DRUG COMPANY, on behalf of itself and all others similarly situated, Plaintiff v. TAKEDA PHARMACEUTICALS U.S.A., INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL INC., WATSON LABORATORIES, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., and AMNEAL PHARMACEUTICALS LLC, Defendants.	Civil Action No. 2:21-cv-03500-MAK

PLAINTIFF VALUE DRUG COMPANY'S JOINT OPPOSITION TO TAKEDA, WATSON AND AMNEAL'S MOTIONS TO DISMISS PLAINTIFF'S COMPLAINT

TABLE OF CONTENTS

I. INTRODUCTION 1

A. Allegations of the Complaint 2

B. Summary of Argument 4

II. ARGUMENT 5

A. Plaintiff Has Adequately Alleged Direct Evidence of Conspiracy 5

1. Signed, Written Agreements are Direct Evidence 5

2. Statements to Judge Andrews Are Direct Evidence 6

3. Communication Among the Generic Defendants Is Not Required 8

B. Plaintiff Has Adequately Alleged Circumstantial Evidence of Conspiracy 9

1. Parallel Behavior 10

2. Consciousness of Others' Conduct 10

3. Motive to Agree 11

4. Actions Contrary to Economic Interests 13

C. Plaintiff Has Adequately Alleged a Single Conspiracy 15

1. All the Conspirators Shared a Common Goal 16

2. The Conspiracy Required Continuing Cooperation 17

3. There Is Substantial Overlap Among the Conspirators 17

D. Takeda's Patents Do Not Immunize the Conspiracy 18

III. CONCLUSION 20

TABLE OF AUTHORITIES

Page(s)

Cases

Adams v. Coppola,
53 Fed. Appx. 661 (3d Cir. 2002) 13

Brunson Commc'ns, Inc. v. Arbitron, Inc.,
239 F. Supp. 2d 550 (E.D. Pa. 2002) 6

Cont'l Ore Co. v. Union Carbide & Carbon Corp.,
370 U.S. 690 (1962) 15

Dey, L.P. v. Sepracor, Inc.,
595 F. Supp. 2d 355 (D. Del. 2009) 3

Fleischman v. Albany Med. Ctr.,
728 F. Supp. 2d 130 (N.D.N.Y. 2010) 14

FTC v. Actavis, Inc.,
570 U.S. 136 (2013) 1, 3, 18

Hartford-Empire Co. v. United States,
323 U.S. 386 (1945) 19

Howard Hess Dental Labs, Inc. v. Dentsply Int'l, Inc.,
602 F.3d 237 (3d Cir 2010) 9

In re Actos End Payor Antitrust Litig.,
2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015) 13, 14

In re AndroGel Antitrust Litig. (No. II),
2018 WL 2984873 (N.D. Ga. June 14, 2018) 6

In re Capacitors Antitrust Litig.,
106 F. Supp. 3d 1051 (N.D. Cal. 2015) 15

In re Flat Glass Antitrust Litig.,
385 F.3d 350 (3d Cir. 2004) 5

In re Generic Pharm. Pricing Antitrust Litig.,
338 F. Supp. 3d 404 (E.D. Pa. 2018) 5, 9

In re High Pressure Laminates Antitrust Litig.,
2006 WL 1317023 (S.D.N.Y. May 15, 2006) 14

In re K-Dur Antitrust Litig.,
338 F. Supp. 2d 517 (D.N.J. 2004) 9

In re Lithium Ion Batteries Antitrust Litig.,
2014 WL 309192 (N.D. Cal. Jan. 21, 2014) 15

In re Niaspan Antitrust Litig.,
42 F. Supp. 3d 735 (E.D. Pa. 2014) 2

In re Processed Egg Prods. Antitrust Litig.,
2016 WL 5539592 (E.D. Pa. Sept. 28, 2016) 9

In re Titanium Dioxide Antitrust Litig.,
959 F. Supp. 2d 799 (D. Md. 2013) 14

In re Wellbutrin XL Antitrust Litig.,
133 F. Supp. 3d 734 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017) 5

In re Westinghouse Sec. Litig.,
90 F.3d 696 (3d Cir. 1996) 4

In re Wholesale Grocery Prods. Antitrust Litig.,
752 F.3d 728 (8th Cir. 2014) 4

In re Xyrem (Sodium Oxybate) Antitrust Litig.,
2021 WL 3612497 (N.D. Cal. Aug. 13, 2021) 10, 11, 12

Ins. Brokerage Antitrust Litig.,
618 F.3d 300 (3d Cir. 2010) 5, 14

Interstate Circuit, Inc. v. United States,
306 U.S. 208 (1939) 8

King Drug Co. of Florence v. Cephalon, Inc.,
88 F. Supp. 3d 402 (E.D. Pa. 2015) 5

King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.,
791 F.3d 388 (3d Cir. 2015) 1, 20

Mannington Mills, Inc. v. Congoleum Indus., Inc.,
610 F.2d 1059 (3d Cir. 1979) 19

McTernan v. City of York,
577 F.3d 521 (3d Cir. 2009) 2

Monsanto Co. v. Spray-Rite Serv. Corp.,
465 U.S. 752 (1984) 9

Moraine Prods. v. ICI Am., Inc.,
538 F.2d 134 (7th Cir. 1976) 19, 20

Morgan Truck Body, LLC v. Integrated Logistics Sols., LLC,
2008 WL 746827 (E.D. Pa. Mar. 20, 2008) 13

Mylan Pharm., Inc. v. FDA,
23 F. Supp. 3d 631 (N.D. W. Va. 2014) 3

Petruzzi's IGA Supermarkets v. Darling-Del. Co.,
998 F.2d 1224 (3d Cir. 1993) 10

Re/Max Int'l, Inc. v. Realty One, Inc.,
173 F.3d 995 (6th Cir. 1999) 14

Reigle v. Reish,
2013 WL 4502104 (M.D. Pa. Aug. 22, 2013) 13

Rossi v. Standard Roofing, Inc.,
156 F.3d 452 (3d Cir. 1998) 5, 6

Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC,
2016 WL 4992690 (S.D.N.Y. Sept. 13, 2016) 2

Takeda Pharm. USA, Inc. v. W.-Ward Pharm. Corp.,
72 F. Supp. 3d 539 (D. Del. 2014) 2

Takeda Pharm. USA, Inc. v. W.-Ward Pharm. Corp.,
785 F.3d 625 (Fed. Cir. 2015) 2

Toys "R" Us v. FTC,
221 F.3d 928 (7th Cir. 2000) 14

TVT Records v. Island Def Jam Music Grp.,
412 F.3d 82 (2d Cir. 2005) 16

United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA,
296 F. Supp. 3d 1142 (N.D. Cal. 2017) 6

United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.,
74 F. Supp. 3d 1052 (N.D. Cal. 2014) 2

United States v. Alicea,
496 Fed. Appx. 192 (3d Cir. 2012) 15

United States v. Greenidge,
495 F.3d 85 (3d Cir. 2007) 17

United States v. Hartford-Empire Co.,
46 F. Supp. 541 (N.D. Ohio 1942) 19

United States v. Hornick,
491 Fed. Appx. 277 (3d Cir. 2012) 15

United States v. Kelly,
892 F.2d 255 (3d Cir. 1989) 16

United States v. Kemp,
500 F.3d 257 (3d Cir. 2007) 17

United States v. Lee,
359 F.3d 194 (3d Cir. 2004) 17

United States v. Masonite Corp.,
316 U.S. 265 (1942) 8

United States v. Padilla,
982 F.2d 110 (3d Cir. 1992) 16

United States v. Salmon,
944 F.2d 1106 (3d Cir. 1991) 18

United States v. Singer Mfg. Co.,
374 U.S. 174 (1963) 18

United States v. U.S. Gypsum Co.,
333 U.S. 364 (1948) 8, 19

United States v. Weiner,
2009 WL 1911286 (E.D. Pa. July 1, 2009) 16

I. INTRODUCTION

Plaintiff plausibly alleges a conspiracy among Defendants to maintain supracompetitive prices for Colcrys and generic Colcrys. The alleged conspiracy's form and function were essentially the same as that described in the complaint sustained by the Supreme Court in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013): a series of bilateral patent settlement and license agreements that delayed generic competition from the 180-day exclusivity holder and subsequent generic applicants beyond what a traditional settlement would have provided. Here, rather than Takeda paying cash to Par, Watson, and Amneal in exchange for their promises to delay entry into the market with generic Colcrys, Takeda and Par instead formed a "joint venture" to share monopoly profits for several years to avoid competing against one another,[1] and Watson and Amneal each received an agreed 135 days of generic Colcrys sales free of competition from firms other than the co-conspirators. Like the FTC's in *Actavis*, Plaintiff's Complaint here alleges a conspiracy in which "the patentee seeks to induce [each] generic challenger to abandon its [patent] claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Id.* at 154.

[1] The Takeda/Par agreement is similar to the one in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015). There, SKB gave Teva a so-called "exclusive" license (even as to SKB's authorized generic) for a period of 6 months, in exchange for Teva's agreement to delay its generic for three years. *Id*. at 397. Since Teva was the first generic company to file an ANDA, under the Hatch Waxman Act the FDA could not approve another ANDA until 180 days after Teva's launch. The SKB/Teva agreement thus bottlenecked all generic competition, extending SKB's monopoly for three years. Similarly here, Takeda agreed to license Par as Takeda's authorized generic beginning July 1, 2018 and continuing until June 30, 2022, on terms designed to effectively preclude meaningful price competition between Takeda's brand Colcrys and Par's generic Colcrys. Takeda Ex. 1, Par License Agreement ¶ 1.1. Just like Teva's in Lamictal, Par's 180-day exclusivity would block competition from other generics until Par launched its authorized generic, delaying competition between July 2016, when the Complaint alleges Par would have launched, and 180 days after July 1, 2018. Compl. ¶ 32. The Par License Agreement contemplated that Par would not launch its own generic Colcrys until January 1, 2024, or the date any third party (*i.e.*, Watson or Amneal) was permitted to launch (October 15, 2020), well beyond the 180-day period provided for under the Hatch Waxman Act. Takeda Ex. 1, Par License Agreement ¶¶ 1.3(a), (c).

A. Allegations of the Complaint

Plaintiff alleges that Par, Watson and Amneal (the "Generic Defendants") sought to compete with Takeda by selling generic versions of Takeda's brand gout drug Colcrys. Compl. ¶¶ 2, 42-43. Takeda sued each, alleging patent infringement. *Id.* ¶ 44. But Takeda's patents were fatally weak, and all Defendants knew it: the Federal Circuit had ruled in May of 2015 that Takeda was unlikely to succeed in proving infringement in the similar *Mitigare* case,[2] and after Judge Robinson's denial of Takeda's motion for a preliminary injunction in November of 2014,[3] Takeda anticipatorily launched an authorized generic Colcrys (in January of 2015) to try to lock up generic Colcrys sales before the inevitable occurred. *Id.* ¶¶ 42-43, 45, 49.[4]

Defendants understood that when the Generic Defendants prevailed in the patent litigation, they would have to compete simultaneously with one another, with Takeda's "authorized generic" (sold by Prasco, *see id.* ¶¶ 49-51 ("AG")), and with every other company that submitted an application ("ANDA") to FDA to sell generic Colcrys (the "Second Wave"). *Id.* ¶¶ 3(a)-(e), 43, 52.[5] This competition would have been ruinous. *Id.* ¶¶ 3(e), 52; *id.* ¶¶ 28-29 (unfettered

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[2] *See Takeda Pharm. USA, Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015).

[3] *See Takeda Pharm. USA, Inc. v. W.-Ward Pharm. Corp.*, 72 F. Supp. 3d 539 (D. Del. 2014).

[4] The Court can take judicial notice of the judicial proceedings and public filings referenced herein. *See McTernan v. City of York*, 577 F.3d 521, 526 (3d Cir. 2009). Plaintiff's averments and evidence that Takeda faced certain defeat are more detailed and plausible than in other cases. *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, 2016 WL 4992690, at *15 (S.D.N.Y. Sept. 13, 2016) (motion to dismiss denied despite no non-infringement or invalidity facts pled); *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1072 & n.25 (N.D. Cal. 2014) (sufficient that plaintiffs pled Judge Sleet's claim construction decision that suggested a noninfringement ruling) (motion to dismiss denied); *In re Niaspan Antitrust Litig.*, 42 F. Supp.3d 735, 755 (E.D. Pa. 2014) (plaintiff pled only circumstantial evidence of patent weakness) (motion to dismiss denied). *See also* Pls.' Opp'n to Par Mot. to Dismiss at Part IV.A.2.

[5] The Second Wave was composed of at least Alkem Labs, Dr. Reddy's, Granules, Hetero Labs Ltd., Mylan, and Zydus. *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022352 ("Therapeutic Equivalents" tab).

competition yielded prices at just 9 cents/tablet *versus* $5.25/tablet). To prevent that price collapse, Defendants conspired to limit output by ordering market entry for the next five and half years. *Id.* ¶¶ 3-4, 53-61. Specifically, Par, which had tentative approval to sell generic Colcrys in February 2015 (*id.* ¶ 46),[6] agreed not to do so until 2024. Takeda Ex. 1, Par License Agreement ¶ 1.3(a).[7] In exchange, Takeda and Par entered into a "joint venture," making Par the distributor of AG Colcrys for several years in lieu of Prasco (starting on July 1, 2018, after a lengthy agreed delay that blocked all other generic Colcrys output for two years, *see id.* ¶¶ 40, 42, 47), and effectively handing Par $50-80 million. *Id.* ¶ 1.1; Compl. ¶¶ 2, 3(a)-(c), 55, 69.

Watson and Amneal, who received tentative approval to sell generic Colcrys in October 2015 and September 2016, respectively but could not launch until 180 days after Par (*id.* ¶¶ 47-48),[8] agreed to wait until October 15, 2020 (over 27 months after Par's AG launch) to begin selling. Takeda Ex. 2, Watson License Agreement ¶ 1.2(a); Takeda Ex. 3, Amneal License Agreement ¶ 1.2(a). Amneal and Watson thus agreed to cede over 21 months of generic sales to Par. Compl. ¶¶ 3(d), 4, 56, 67. In exchange, Takeda promised not to license any Second Wave ANDA filer, and not to launch a second AG of Colcrys, until March 4, 2021, 135 days after Watson and Amneal's delayed entry date. *Id.* ¶ 3(e); Takeda Ex. 2, Watson License Agreement ¶¶ 1.2(b) &

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[6] A tentatively approved ANDA meets all requirements for final approval, but an exclusivity remains. FDA, ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs 4 (Sept. 2020), available at https://www.fda.gov/media/119718/download. Takeda's exclusivity expired on July 29, 2016. Compl. ¶ 32.

[7] Par could also launch a generic Colcrys on the same day as a "Third Party," which by operation of the Watson Agreement would be 135 days before any member of the Second Wave. *Id.* ¶ 1.3(c); Takeda Ex. 2, Watson Agreement ¶ 1.2(b).

[8] *See Actavis*, 570 U.S. at 143-44, 154-56 (explaining 180-day exclusivity provision); *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 357-58 (D. Del. 2009) (same). Par's sale of AG Colcrys triggered the running of this 180-day exclusivity period. *See Mylan Pharm., Inc. v. FDA*, 23 F. Supp. 3d 631, 645 (N.D. W. Va. 2014).

(f); Takeda Ex. 3, Amneal License Agreement ¶¶ 1.2(c) & (d).[9]

The conspiracy was worth $50-80 million to Par, $12-36 million each to Watson and Amneal, and about $1 billion to Takeda, all at the expense of purchasers. Compl. ¶¶ 58-59, 69-71.

B. Summary of Argument

Besides impermissibly contradicting the Complaint and downplaying the clear language of their written agreements,[10] Defendants' primary argument is that Plaintiff has not adequately pled circumstantial evidence of conspiracy. Defendants are wrong, because Plaintiff has not just pled adequate circumstantial evidence, but has pled *direct* evidence of conspiracy (in the forms of written and signed agreements and judicial admissions by Par and Takeda) that renders the circumstantial evidence superfluous. Defendants argue that Plaintiff has not alleged a single conspiracy. Not so. Moreover, at this stage, the question is not the nature of the conspiracy or its precise participants (a question for the finder of fact), but instead whether Plaintiff has plausibly alleged conspiracy. Finally, Takeda argues that its Colcrys patents immunize it from antitrust scrutiny. That argument contradicts controlling Supreme Court and Third Circuit law, in cases strikingly similar to this one, alleging that a group of patentees and alleged infringers used patent

[9] Amneal was promised the benefit of the 135-day provision from the Watson Agreement by operation of ¶ 1.2(c) of the Amneal License Agreement.

[10] Although the written agreements fully support Plaintiff's complaint, and *a fortiori* can "bear the construction placed on them by plaintiff[]," *see In re Westinghouse Sec. Litig.*, 90 F.3d 696, 713 (3d Cir. 1996), this is an antitrust case, not a contract case, and so the written agreements place no ceiling on what Plaintiff may plead and ultimately prove. *See In re Wholesale Grocery Prods. Antitrust Litig.*, 752 F.3d 728, 734 (8th Cir. 2014) ("But this is not a contracts case in which the scope of the alleged anticompetitive agreement is cabined by the four corners of the written document. Not confined by the parol evidence rule, [plaintiff] could use all manner of extrinsic evidence to persuade a jury that what the wholesalers *actually agreed to* was a naked division of territory and customers. And the record contains enough evidence, viewed in the light most favorable to [plaintiff], potentially to convince a reasonable jury of this fact.") (summary judgment denied) (emphasis in original).

settlement and license agreements to restrict other firms from causing ruinous price competition.

II. ARGUMENT

The legal standard on a Rule 12(b)(6) motion is familiar. "On a motion to dismiss, the Court considers plausibility, not probability. In other words, Plaintiffs are not required to plead facts that, if true, definitely rule out all possible innocent explanations. Rather, to withstand dismissal, Plaintiffs must state enough facts to raise a reasonable expectation that discovery will reveal evidence of illegal agreement even if the court believes such proof is improbable." *In re Generic Pharm. Pricing Antitrust Litig.*, 338 F. Supp. 3d 404, 435 (E.D. Pa. 2018) (cleaned up).

A. Plaintiff Has Adequately Alleged Direct Evidence of Conspiracy

Circumstantial allegations of conspiracy are unnecessary if direct evidence is pled. *See In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 323-24 (3d Cir. 2010); *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 n.7 (3d Cir. 2004); *Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 466 (3d Cir. 1998). "Direct evidence of a conspiracy is evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted," for example, "a document or conversation explicitly manifesting the existence of the agreement in question." *Ins. Brokerage*, 618 F.3d at 324 n.23. Here, there are both documents *and* conversations.

1. Signed, Written Agreements are Direct Evidence

First, there are signed, written agreements, reviewed above, including settlement agreements and license agreements between Takeda and each of the Generic Defendants. *See In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 770 (E.D. Pa. 2015) ("A signed agreement is direct evidence of a conspiracy. * * * Because direct evidence of an agreement exists in the form of the Wellbutrin Settlement, however, [a circumstantial evidence] analysis under *Matsushita* is inappropriate."), *aff'd*, 868 F.3d 132 (3d Cir. 2017); *id.* at 745 (describing series of bilateral settlement and license agreements comprising the so-called Wellbutrin Settlement); *King Drug*

Co. of Florence v. Cephalon, Inc., 88 F. Supp. 3d 402, 410 n.9 (E.D. Pa. 2015) ("Plaintiffs have presented direct evidence of concerted action through the settlement agreements between Cephalon and each of the Generic Defendants"); *In re AndroGel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *8 (N.D. Ga. June 14, 2018) ("the settlements are clear, direct evidence of an agreement to unlawfully restrain trade. Not only is there enough evidence for a jury to find that there was an agreement, it is doubtful that a reasonable jury could find otherwise."); *id.* at *3-4 (describing bilateral settlement and other agreements); *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1165 (N.D. Cal. 2017) (based on signed settlement agreement among brand and generic competitors, granting plaintiff judgment as a matter of law on the issue of conspiracy).[11]

2. Statements to Judge Andrews Are Direct Evidence

Second, there are "graphic and extensive … statements and actions of various defendants directed towards eliminating … price-cutting competitor[s] … who threatened to destabilize the market." *Rossi*, 156 F.3d at 457. Specifically, during Takeda's injunction action seeking to prevent a generic Colcrys Second Wave launch until 135 days after Watson and Amneal entered (*i.e.*, until March 4, 2021), Takeda admitted to Judge Andrews that the conspiracy challenged here forestalled "full generic competition" for the benefit of the Generic Defendants, explaining that "there is a date certain that there will be full generic competition for this product. The agreement, though, does provide that Par, Amneal and Watson get a better deal." Hr'g Tr. of Jan. 21, 2020 at 68:5-15, *Takeda Pharm., U.S.A., Inc. v. Mylan Pharm., Inc.*, No. 19-cv-2216 (D. Del. Feb. 4, 2020) (ECF No. 126). Takeda made similar statements in writing, admitting that the "[Second Wave]

[11] *Brunson Commc'ns, Inc. v. Arbitron, Inc.*, 239 F. Supp.2d 550 (E.D. Pa. 2002), cited by Defendants, is inapposite. There, "[p]laintiff ha[d] identified none of the entities which allegedly conspired with Defendant." *Id*. at 562.

license triggers take into account Takeda's previous settlements with Par, Watson, and Amneal (the 'Earlier Filers')" and that "[the Mylan agreement] allows Mylan to launch early if another generic filer licensed by Takeda (other than the Earlier Filers) enters the market with a generic product … [or] [REDACTED] after the Earlier Filers are allowed to launch their generic Colcrys products." Opening Br. in Supp. of Takeda's Mot. for a Prelim. Inj. at 8, *Takeda Pharm. U.S.A., Inc., v. Mylan Pharm. Inc.*, No. 19-cv-2216 (D. Del. Dec. 5, 2019) (ECF No. 103).[12] The Court can take judicial notice of all of this.

Par's statements to Judge Andrews likewise conceded the purpose and effect of the conspiracy and the "joint venture" Takeda offered Par:

> this mutually beneficial arrangement with a single branded drug (Takeda's Colcrys) and a single generic version (Par's authorized generic) only functions if the market for Colcrys-equivalent colchicine is limited to those two products. Although a drug market can maintain price stability with a single generic version of a drug on the market, multiple entrants often produce a market-wide price collapse with mass renegotiation and cancellation of supply agreements. The distribution agreement between Takeda and Par . . . provides powerful incentives to ensure that the parties preserve the two-entrant market.

Compl. ¶ 58 (quoting Mem. in Supp. of Par Pharm. Inc.'s Mot. to Intervene at 4-5, *Takeda Pharm. U.S.A., Inc., v. Mylan Pharm. Inc.*, No. 19-cv-2216 (D. Del. Dec. 23, 2019) (ECF No. 31)).[13] Par conceded to Judge Andrews that the goal of the conspiracy was to tie Takeda's hands and prevent generic competition for the Generic Defendants' benefit:

> the Takeda-Par agreements ensure Par's exclusivity by subjecting Takeda to severe consequences if it authorizes another generic. For example, a failure by Takeda to enforce exclusivity would

[12] Based on the Watson License Agreement, the redacted language likely reads "135 days."

[13] That Par wished to preserve its two-competitor arrangement as long as possible does not, as Watson and Amneal suggest, negate that Watson and Amneal stood to benefit from a market limited to three generics (co-conspirators Watson, Amneal, and Par) rather than being subjected to competition from nine. *See infra* note 20 & accompanying text.

> authorize Par to launch its own ANDA product royalty-free, effectively subjecting Takeda to the damage that Mylan threatens here and that Takeda sues to avoid.

Reply in Supp. of Par Pharm. Inc.'s Mot. to Intervene at 9, *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, No. 19-cv-2216 (D. Del. Jan. 1, 2020) (ECF No. 82).[14]

3. Communication Among the Generic Defendants Is Not Required

Contrary to Defendants' arguments, to plead direct evidence of a horizontal (as opposed to vertical) conspiracy, Plaintiff need not allege communication or coordination among all the Defendants. Indeed, in none of *Wellbutrin XL*, *King Drug*, or *AndroGel*, *supra*, were written agreements or statements among the generic drug companies required to be pled or proven, yet summary judgment on the element of conspiracy was denied in each. In *United States v. Masonite Corp*., the Supreme Court concluded that successive, independently negotiated bilateral licensing agreements in which the licensees (who were would-be horizontal competitors) had no discussions with each other nevertheless supported a finding of conspiracy:

> It is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators. Acceptance by competitors, without previous agreement, of an invitation to participate in a plan, the necessary consequence of which, if carried out, is restraint of interstate commerce, is sufficient to establish an unlawful conspiracy under the Sherman Act.

316 U.S. 265, 275 (1942) (quoting *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 277 (1939)). *See also United States v. U.S. Gypsum Co.*, 333 U.S. 364, 394 (1948) ("when a group of competitors enters into a series of separate but similar agreements with competitors or others, a strong inference arises that such agreements are the result of concerted action."). *See also* Part II.C., *infra* (evidence that Defendants formed a single conspiracy).

[14] Par's reasoning and the leverage it references apply equally to Watson and Amneal.

Judge Greenaway applied the rule of *Masonite* in denying the motion to dismiss in *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004), rejecting defendants' argument that just two bilateral agreements between the brand company, Schering, and each of two generic competitors, and not a "three party conspiracy," had been pled. *Id.* at 536-39. More recently, in *In re Generic Pharm. Pricing Antitrust Litig.*, Judge Rufe rejected defendants' arguments that plaintiff had not adequately pled direct evidence of conspiracy between drug makers Heritage, Mayne and Mylan, where plaintiff pled only "supposed communications between Mayne and Heritage, and separately between Mylan and Heritage" and not a "*three-way* meeting of the minds." 338 F. Supp. 3d at 440 (emphasis in original). Judge Rufe held that direct evidence of conspiracy had been adequately pled, criticized defendants for "ask[ing] too much in the current procedural posture of this litigation," and refused dismissal. *Id.*[15]

B. Plaintiff Has Adequately Alleged Circumstantial Evidence of Conspiracy

Although direct evidence of conspiracy renders it superfluous, Plaintiff has also pled circumstantial evidence of conspiracy, with allegations that "tend to exclude the possibility that the [defendants were] acting independently." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S.

[15] Plaintiff's allegations here stand in contrast to those of the losing indirect purchaser plaintiffs in *Howard Hess Dental Labs, Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237 (3d Cir 2010), who failed in their second attempt to allege a vertical hub-and-spoke conspiracy between Dentsply and 26 of its dealers in the hope of triggering a co-conspirator exception to the direct purchaser rule. *Dentsply* is limited to such *vertical* buyer-seller conspiracies. *See In re Processed Egg Prods. Antitrust Litig.*, 2016 WL 5539592, at *12 (E.D. Pa. Sept. 28, 2016) ("The Plaintiffs' theory and evidence in this case involves no *vertical* agreements between a buyer and seller," so *Dentsply* and "the 'hub and spoke' cases which require further evidence of agreement between the 'spokes' are distinguishable") (emphasis added). Moreover, in *Dentsply*, unlike here (*see* Part II.B., *infra*), the plaintiffs did not allege any "plus factors"; instead, they did "no more than intimate merely parallel conduct that could just as well be independent action." 602 F.3d at 256 (quotation omitted). Nor did they, as Plaintiff does here, allege any facts plausibly suggesting that the dealers "knew about the alleged plan to maintain Dentsply's market position." *Id.* at 255. *See* Part II.B.1.-2., *infra*. Had they done so, they would have "survive[d] dismissal." *Id.*

752, 768 (1984). Circumstantial evidence is "parallel behavior" supplemented by additional evidence from which an illegal agreement can be inferred. *See Petruzzi's IGA Supermarkets v. Darling-Del. Co.*, 998 F.2d 1224, 1242 (3d Cir. 1993). Allegations suffice "(1) that the defendants' behavior was parallel; [and] (2) that the defendants were conscious of each other's conduct and that this awareness was an element in their decision-making process." *Id*. at 1243. The "additional evidence" consists of "certain 'plus' factors, including (1) actions contrary to the defendants' economic interests, and (2) a motivation to enter into such an agreement." *Id*.

1. Parallel Behavior

Plaintiff has alleged that Par, Amneal and Watson all similarly agreed with Takeda to restrict their output of generic Colcrys instead of competing. Compl. ¶¶ 2-4, 54-57. The various written agreements show not only that they were negotiated simultaneously and contain similar provisions (conditions under which generic Colcrys output would be restricted and permitted), but also that they refer to one another. *See* Takeda Ex. 1, Par License Agreement at 1 (executed Nov. 24, 2015); Takeda Ex. 2, Watson Settlement Agreement at 1 (referring to Dec. 9, 2015 term sheet, just 15 days later); Takeda Ex. 3, Amneal License Agreement at 1 (referring to Dec. 10, 2015 term sheet, just 16 days later than Par and just one day later than Watson); Takeda Ex. 2, Watson License Agreement ¶ 1.2(b)-(c) (Watson agreement on generic entry expressly refers to Par and Amneal).

2. Consciousness of Others' Conduct

The simultaneousness and similarity of the written agreements, and the references to Par and Amneal in Watson's License Agreement (*see* Part II.B.1, *supra*), demonstrate Defendants' knowledge of one another's conduct. *E.g.*, *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 2021 WL 3612497, at *28 (N.D. Cal. Aug. 13, 2021) ("Given [the brand's] public and tightly sequenced settlements of longstanding patent cases, Defendants had reason to know that other Generic Defendants were involved in the same broad project of market allocation.") (internal quotation

marks omitted). In addition, Takeda's statements to Judge Andrews — specifically that the "Earlier Filers" (the group comprising the Generic Defendants) collectively enjoyed "a better deal" (*see* Part II.A.2., *supra*) — imply knowledge among the Generic Defendants of one another and of the conspiracy's aim to benefit the co-conspirators by restricting "outsiders." That Judge Robinson simultaneously cancelled the December 9, 2015 trials between Takeda on the one hand and Watson and Amneal on the other, following the very same status conference among all of them, and just nine days after staying the Par action in light of the Takeda-Par settlement, certainly suggests that Takeda and the Generic Defendants treated one another as a discrete group for purposes of the written agreements. Order, *Takeda Pharm. USA Inc. v. Par Pharm. Cos. Inc.*, No. 13-cv-01524 (D. Del. Nov. 30, 2015); Minute Entry, *Takeda Pharm. USA Inc. v. Watson Labs. Inc.*, No. 14-cv-00268 (D. Del. Dec. 9, 2015); Minute Entry, *Takeda Pharm. USA Inc. v. Amneal Pharm. LLC*, No. 13-cv-01729 (D. Del. Dec. 9, 2015).

3. Motive to Agree

The Complaint alleges a pecuniary motive for each Defendant to join the conspiracy. Compl. ¶¶ 52-53, 58, 68-71. "[T]he market entry of additional generic versions of a brand drug results in increasingly robust price competition." *Id.* ¶ 52. This is well known. *Id.* ¶ 59 (Par assertion). *See also* FDA, "Generic Competition and Drug Prices" (Gerstein Decl. Ex. A). By conspiring to order their market entry, Takeda avoided competing against Par, Watson, and Amneal for a period of time, then competed against just the three co-conspirators and avoided a price collapse from the looming Second Wave. Compl. ¶¶ 3, 53, 67-71. Par avoided competing against Takeda's authorized generic during its 180-day exclusivity period, then avoided competing with Watson and Amneal for a lengthy period thereafter, and then competed against just the three other co-conspirators and avoided a price collapse from the looming Second Wave. *Id*. And Watson and Amneal avoided competing with the Second Wave for 135 days after their launch. *Id*.

The Complaint even quantifies the pecuniary benefit each Defendant expected from the conspiracy relative to the price collapse that would have resulted without it. *Id.* ¶¶ 69-71. Takeda and Par's motions do not dispute these allegations, but Watson and Amneal argue that the allegation that they each earned $12-36 million by conspiring is implausible and contradicted by the actual agreements. Even if this challenge were the proper subject of a motion to dismiss (it is not), simple arithmetic using the averments of the Complaint and matters of public record of which the Court can take judicial notice shows the plausibility of Plaintiff's averments, and confirms that Watson and Amneal could each expect to earn around $22 million more during their 135-day period selling as a group of just three generics (Watson, Amneal, and AG Colcrys sold by Par) compared with selling against the Second Wave for that same period of time:

Watson and Amneal each as 1 of 3 generics for 135 days under the conspiracy	**Watson and Amneal each as 1 of 9 generics for 135 days without the conspiracy**
Total annual brand Colcrys sales = $546MM[16]	Total annual brand Colcrys sales = $546MM
Generic volume = 90% = $491.4MM[17]	Generic volume = 90% = $491.4MM
3-generic price % of brand price = 44% = $216.21MM[18]	9-generic price % of brand price = 20% = $98.29MM[19]
135 days instead of 365 = 37% = $80MM	135 days instead of 365 = 37% = $36.36MM
Each generic gets one third = 33.33% = $26.66MM	Each generic gets one ninth = 11.11% = $4.03MM
Additional dollar sales for each of Watson and Amneal under the conspiracy: **$22.63MM**	

Thus, Watson and Amneal could each expect to earn approximately **$22.63** million more under the output-restriction conspiracy as compared to without the conspiracy over the same period of

[16] Compl. ¶ 29.

[17] *See* "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," An FTC Staff Study, at p. 8 (Jan. 2010) (one year after generic entry, generics on average accounted for 90% of combined brand and generic sales).

[18] *See* FDA, "Generic Competition and Drug Prices" (Gerstein Decl. Ex. A) (3-generic price is 44% of pre-generic brand price).

[19] *See id.* (9-generic price is just 20% of pre-generic brand price).

time (because $26.66 million - $4.03 million = $22.63 million), which falls at the midpoint of the range Plaintiff pled. Compl. ¶ 71. Watson and Amneal's argument is both inapt and incorrect.[20]

4. Actions Contrary to Economic Interests

Plaintiff has adequately pled that each Defendant's conduct, and in particular the agreements they signed, make economic sense only when viewed in the context of their conspiratorial interests, rather than their unilateral interests. *See* Compl. ¶¶ 57, 60(a)-(c). It was against Takeda's unilateral economic interests to have its AG distributor, Prasco, exit the market. *Id.* ¶ 60(a). It was against Par's unilateral economic interests to restrict its output of generic Colcrys for several years. *Id.* ¶ 60(b). It was against Watson's and Amneal's unilateral economic interests to restrict their output of generic Colcrys for several years after Par's 180-day exclusivity elapsed. *Id.* ¶ 60(c). These actions only make sense if the output-restriction conspiracy existed and allowed Defendants to benefit from the restricted competition it wrought. *Id.* ¶¶ 60, 67-71. A provision common to the written agreements underscores this dynamic, by providing that the Generic Defendants could bring their generic Colcrys to market immediately if others did. *Id.* ¶ 57.[21] These averments likewise distinguish this case from *In re Actos End Payor Antitrust Litig.*,

[20] Watson and Amneal's argument that Plaintiff incorrectly surmised that the written agreements would have their periods of limited competition running longer and consecutively not concurrently (Compl. ¶¶ 56, 71) thus fails to detract from the gravamen or plausibility of this case, much less compel dismissal, and Defendants cite nothing to the contrary. *See Reigle v. Reish*, 2013 WL 4502104, at *3 (M.D. Pa. Aug. 22, 2013) ("the claims set forth provide a basis for the claims alleged without the need to include further details") (motion to amend complaint denied); *Morgan Truck Body, LLC v. Integrated Logistics Sols., LLC*, 2008 WL 746827, at *3 (E.D. Pa. Mar. 20, 2008) (complaint need not include evidentiary detail; plaintiff merely has to allege a factual predicate concrete enough to warrant further proceedings). Immaterial errors do not render a Complaint "rambling" or "replete with typographical and grammatical errors" or unable "cogently to articulate its apparent claims." *See Adams v. Coppola*, 53 Fed. Appx. 661, 661 (3d Cir. 2002).

[21] The "escape clauses" in each written agreement (Takeda Ex. 1, Par License Agreement ¶¶ 1.3(c) & (d); Takeda Ex. 2, Watson License Agreement ¶¶ 1.2(b), (c) & (f); Takeda Ex. 3, Amneal License Agreement ¶¶ 1.2(c) & (d)) are telltale economic evidence that restricting output was not

cont'd…

2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015), where "Plaintiffs have not … plausibly alleged that the agreements were against Defendants' self-interest in the absence of similar behavior by its rivals, which would [have] suggest[ed] that each Defendant ... received assurances that all its rivals would act similarly." *Id.* at *25 (cleaned up).

Whether Defendants did, in fact, act contrary to their unilateral interests is a jury question, not susceptible to determination on a motion to dismiss. *E.g.*, *Re/Max Int'l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1009-10 (6th Cir. 1999); *In re High Pressure Laminates Antitrust Litig.*, 2006 WL 1317023, at *2 (S.D.N.Y. May 15, 2006) ("The jury is ultimately free to agree with Defendants on this issue [of whether sharing cost data information was against the defendants' unilateral economic interests], but there are genuine disputed issues of fact"); *Fleischman v. Albany Med. Ctr.*, 728 F. Supp. 2d 130, 160-61 (N.D.N.Y. 2010) (same); *In re Titanium Dioxide Antitrust Litig.*, 959 F. Supp. 2d 799, 828 (D. Md. 2013) ("[t]hese debates [over whether defendants acted contrary to their independent interests] reflect genuine issues of material fact") (citation omitted). Thus, even if the direct evidence of conspiracy were absent and it was therefore appropriate to require

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in the unilateral interests of any Generic Defendant, and only makes economic sense if the alleged output-restriction conspiracy did, in fact, exist. (Otherwise, why would a Generic Defendant want to stop sitting on the sidelines and launch its generic Colcrys immediately if others launched, too?) This is precisely the relevance of such promises as recognized by the Third Circuit. *See Ins. Brokerage*, 618 F.3d at 331-32 (citations omitted) (distinguishing *Toys "R" Us v. FTC*, 221 F.3d 928 (7th Cir. 2000) and *Interstate Circuit*, *supra*). But unlike here, plaintiffs in *Ins. Brokerage* pled themselves out of court by alleging that the insurers would agree to the bid rigging conspiracy regardless of whether other insurers agreed or not. *Id.* at 328 ("According to plaintiffs' own account … each insurer had an obvious incentive to enter into the strategic partnerships offered by the defendant brokers, *irrespective of the actions of its competitors*.") (emphasis added); *id.* at 329 n.26 ("insurers had much to lose if they did not become a strategic partner, which provided each of them with an independent business reason to pay brokers contingent commissions"); *id.* at 333 ("[e]ach insurer's share of the market … depended on its ability to gain the broker's favor, not on the choices of its competitors."); *id*. at 334 n.30 ("the allegations . . . do not imply that any [insurer's] agreement with [a broker] was dependent on the conduct of its competitors"). Defendants' attempts to analogize this case to the facts of *Ins. Brokerage* therefore fail, even if Plaintiff lacked direct evidence and was required to resort to circumstantial evidence of conspiracy.

Plaintiff to plead circumstantial evidence of conspiracy, Plaintiff has done so.

C. Plaintiff Has Adequately Alleged a Single Conspiracy

"The character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962) (judgment as a matter of law reversed). Ignoring this principle, Defendants argue that the Complaint must be dismissed because it does not adequately allege a single conspiracy. But at the motion to dismiss stage, the question is not the precise scope or membership of the conspiracy Plaintiff has alleged, but simply whether Plaintiff has plausibly alleged any conspiracy at all. Those are different questions. *See United States v. Alicea*, 496 Fed. Appx. 192, 195 n.3 (3d Cir. 2012) (question "whether a particular individual was a member of a documented conspiracy" is different from question "whether a conspiracy existed at all"); *In re Capacitors Antitrust Litig.*, 106 F. Supp. 3d 1051, 1063 (N.D. Cal. 2015) (denying motion to dismiss claim of single conspiracy because "there simply is no requirement that an antitrust plaintiff draw the boundaries of the alleged conspiracy (or conspiracies) in a complaint with the precision of a diamond cutter. And mere size or breadth alone is not a reason to peremptorily jettison a conspiracy allegation. * * * So long as an alleged conspiracy is supported by enough facts to make it plausible, as it is here, it is of no matter whether it involves three conspirators or a score or more.") (citations omitted); *In re Lithium Ion Batteries Antitrust Litig.*, 2014 WL 309192, at *2 (N.D. Cal. Jan. 21, 2014) ("The question in this case is not whether any conspiracy existed, only how far it reached. That question is ultimately one of fact, and cannot be resolved" on a motion to dismiss).

The question whether a single conspiracy has been adequately charged or proven is a jury question in this Circuit, inappropriate for summary disposition. *See United States v. Hornick*, 491

Fed. Appx. 277, 289 (3d Cir. 2012) ("As a general matter, the issue of whether a single conspiracy or multiple conspiracies exist is a fact question to be decided by a jury") (citations omitted); *United States v. Weiner*, 2009 WL 1911286, at *5 (E.D. Pa. July 1, 2009) ("the existence of a single conspiracy or multiple conspiracies hinges on factual issues that arise at trial"). The related question whether a series of writings — such as the various written agreements between Takeda and each of the Generic Defendants — comprise a single transaction or multiple ones is likewise a question of fact. *See TVT Records v. Island Def Jam Music Grp.*, 412 F.3d 82, 89 (2d Cir. 2005) (it is "typically a question of fact for the jury" whether writings are part of a single transaction or not); 11 Williston on Contracts § 30:26 (4th ed.) ("whether separate agreements are actually part of a single transaction is a question of fact, dependent on the intent of the parties"). For these reasons, Defendants' challenge to the "single-ness" of the alleged conspiracy is inapt.

Nevertheless, Plaintiff has adequately alleged a single conspiracy. To distinguish between single and multiple conspiracies, the Third Circuit considers three factors (the "*Kelly* factors"): (1) whether the conspirators shared a common goal; (2) whether the agreement contemplated bringing to pass a continuous result that will not continue without the continuous cooperation of the conspirators; and (3) the extent to which the participants overlap in the various dealings. *See United States v. Kelly*, 892 F.2d 255, 259 (3d Cir. 1989). The absence of one of the *Kelly* factors, however, does not necessarily defeat the existence of a single conspiracy. *See United States v. Padilla*, 982 F.2d 110, 115 (3d Cir. 1992). Plaintiff's Complaint pleads all three.

1. All the Conspirators Shared a Common Goal

As detailed in Parts II.A.2. and II.B.3, *supra*, the conspiracy's purpose was to avoid a price collapse from unrestricted generic Colcrys competition and thereby allow the conspirators to make money from supracompetitive prices. Courts have repeatedly found this prong satisfied where, as here, the common goal of the conspiracy was to make money through allegedly illegal conduct.

See United States v. Greenidge, 495 F.3d 85, 93 (3d Cir. 2007) ("evidence of a common goal among these co-conspirators: to make money by depositing stolen and altered corporate checks"); *United States v. Lee*, 359 F.3d 194, 208 (3d Cir. 2004) (defendants "shared a common goal, namely to receive shares of [bribes] from boxing promoters."). This factor is therefore pled adequately.

2. The Conspiracy Required Continuing Cooperation

The second *Kelly* factor is often referred to as "interdependence":

> [i]n order to determine whether a group of individuals engaged in a single conspiracy or multiple conspiracies, we evaluate … whether the agreement contemplated bringing to pass a continuous result that ***will not continue without the continuous cooperation of the conspirators***[.] * * * In evaluating interdependence, we consider how helpful one individual's contribution is to another's goals. * * * [I]nterdependence serves as evidence of an agreement; that is, it helps establish whether the alleged coconspirators are all committed to the same set of objectives in a single conspiracy.

United States v. Kemp, 500 F.3d 257, 287, 289 (3d Cir. 2007) (citations and quotations omitted) (emphasis added). *See also* Areeda & Hovenkamp, ANTITRUST LAW ¶ 1411 (1986) ("One firm's actions are interdependent with those of another when their utility depends on the other firm's response."). Here, it is obvious that the requisite interdependence has been plausibly alleged. The supracompetitive pricing of Colcrys and generic Colcrys — the common goal of the conspiracy — depended on the Generic Defendants' agreement to delay selling generic Colcrys and on Takeda's agreement to ensure that it did not license the Second Wave generics to enter until several years after the Defendants had enjoyed their respective periods of limited generic (and AG) Colcrys competition. Compl. ¶¶ 3(a)-(e), 53-56. Obversely, each Generic Defendant's agreement to restrict its own output was expressly dependent on the willingness of the other Generic Defendants to do so. *Id.* ¶ 57. It is difficult to imagine a stronger inference of interdependence.

3. There Is Substantial Overlap Among the Conspirators

The "overlap" factor is also satisfied. As argued in Parts II.A.2. and II.B.1.-2. above,

Takeda treated the Generic Defendants collectively as the group who got a "better deal"; the Generic Defendants negotiated with Takeda simultaneously; their respective written agreements with Takeda were executed roughly simultaneously; and the Watson License Agreement even mentions Par and Amneal. *See e.g.*, *United States v. Salmon*, 944 F.2d 1106, 1118 (3d Cir. 1991) (overlap and single conspiracy found where "at least one member" of the scheme was involved in each challenged transaction.). This factor is therefore satisfactorily pled.

Although the factual question whether Plaintiff challenges a single conspiracy or separate ones is a jury question, at the appropriate stage of these proceedings Plaintiff will produce sufficient evidence to allow a reasonable jury to find a single conspiracy on the basis of *Kelly*.

D. Takeda's Patents Do Not Immunize the Conspiracy

Takeda argues Defendants are immunized from antitrust scrutiny by virtue of Takeda's Colcrys patents. A long line of controlling Supreme Court and Third Circuit decisions says just the opposite. Worse for Defendants, many of the cases are strikingly similar to this one: one or more patentees and several alleged infringers settle their patent disputes and in so doing try to capture the market for themselves as "insiders" to prevent "ruinous" price competition from "outsider" firms. In each, the very same "patent immunity" defense that Takeda raises here was roundly rejected. *See Actavis*, 570 U.S. at 147 (that anticompetitive effects of patent settlement agreements might fall within the scope of the exclusionary potential of the patent cannot immunize the agreements from antitrust attack); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 189, 194-95 (1963) (Singer violated § 1 of the Sherman Act by entering into patent settlement and license agreements with a Swiss firm and a German firm in a single conspiracy to protect the three of them from less-expensive competition from Japanese "outsiders" who would otherwise cause a price collapse); *id.* at 194 ("Singer … was protecting Gegauf and Vigorelli, the sole licensees under the

patent at the time, under the same umbrella. This the Sherman Act will not permit."); *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 388-89, 400 (1948) (even assuming "the validity of all the patents involved," series of bilateral patent infringement settlements and licenses for gypsum board, where "the licensee was protected against competition" and had "knowledge … of the adherence of others" violated § 1 of the Sherman Act); *id.* at 392-93 (district court erred in holding that patent grant immunized conspiracy); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 398, 401-02 (1945) (Hartford's patent settlement and license agreements with Owens, Hazel, Thatcher and Ball over glass-making machinery, effectuating output restrictions intended to stabilize prices and prevent a price collapse from outsider firms, were an illegal conspiracy violating § 1 of the Sherman Act);[22] *Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059, 1073 (3d Cir. 1979) (restriction of competition from outsider "in concert with competing [patent] licensees, is not entitled to an antitrust exemption" because "there is a greater risk that the restriction is designed not to reward the patent monopoly, but to increase the licensee's reward,"[23] and so "we conclude that the fact that Congoleum is a patentee does not justify a special antitrust exemption for the conduct alleged here."). *See also Moraine Prods. v. ICI Am., Inc.*, 538 F.2d

[22] In extensive findings and conclusions that the Supreme Court directly (and unanimously) affirmed, the district court in *Hartford-Empire Co.* rejected Hartford's defense that its output-restriction agreements were perfectly lawful in light of its various patents and the patent infringement disputes those agreements settled. *See United States v. Hartford-Empire Co.*, 46 F. Supp. 541, 546 (N.D. Ohio 1942). The district court reasoned that price stabilization was more important to the firms than settling patent litigation (*id.* at 562), and described the series of patent infringement lawsuits that Hartford (like Takeda here) brought against firms "outside" the conspiracy as motivated by a desire to effectuate "stabilization in the industry[.]" *Id.* at 565. "The ultimate goal of stabilization … appears to have been a quieting and levelling off of competition for the ultimate purpose of attaining price stability in a price structure that would be highly remunerative to the [conspiring] parties concerned." *Id.* at 589.

[23] *Cf.* Compl. ¶¶ 3(e), 60(a), 69, 71 (increasing Par, Watson and Amneal's respective rewards). *See also* Part II.A.2, *supra* (Par's statements to Judge Andrews about the reward to Par and the "severe consequences" to Takeda).

134, 143 (7th Cir. 1976) ("we are not aware of any language specifically creating a theory of unswerving supremacy of patent law over antitrust law nor establishing in a patent licensing situation an absolute immunity from antitrust law"); *id.* at 145 ("Where a patent license is used to protect the licensee in addition to the patentee or is used to allow the licensees to divide a market among themselves, thus enabling them jointly to regiment an industry under the guise of a patent license, there is good reason to declare such a restrictive scheme illegal.").

Takeda's argument that its right to grant "exclusive" licenses confers immunity is likewise incorrect. First, the licenses at issue were expressly termed "nonexclusive." Takeda Ex. 1, Par License Agreement ¶¶ 1.1, 1.2; Takeda Ex. 2, Watson License Agreement ¶ 1.1(a); Takeda Ex. 3, Amneal License Agreement ¶ 1.1. Second, exclusive patent licenses are not immune from antitrust scrutiny. *See Smithkline Beecham Corp.*, 791 F.3d at 407-08; *Moraine Prods.*, 538 F.2d at 143 ("The bare language of § 261 does allow a patentee or his assignee to grant an exclusive license …[.] But the statutory language must be construed in connection with antitrust law.").

III. CONCLUSION

For the reasons above, the motions of Takeda and Watson/Amneal should be denied. If the Court is inclined to grant either motion in any respect, Plaintiff respectfully requests leave to replead.

Dated: November 15, 2021

Respectfully submitted,

VALUE DRUG COMPANY

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CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2021, I caused a copy of the foregoing to be served by email on counsel for each Defendant.

Dated: November 15, 2021

/s/ Bruce E. Gerstein
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